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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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09/937,499

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Konstantin Petrukhin

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05/24/2006

MERCK AND CO., INC

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EXAMINER

JUEDES, AMY E

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 05/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                  |                                  |  |
|------------------------------|----------------------------------|----------------------------------|--|
| <b>Office Action Summary</b> | Application No.<br>09/937,499    | Applicant(s)<br>PETRUKHIN ET AL. |  |
|                              | Examiner<br>Amy E. Juedes, Ph.D. | Art Unit<br>1644                 |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 September 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-21 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
       Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
       Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

1. Restriction is required under 35 U.S.C. 121 and 372.
2. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.
3. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-6 and 16, drawn to an isolated DNA encoding a KCNQ5 protein, vectors and host cells comprising said DNA, isolated DNA that hybridizes to SEQ ID NO: 1 or 2, and probes comprising at least 18 nucleotides of SEQ ID NO: 1 or 2.

Group II, claims 7-10, drawn to an isolated KCNQ5 protein.

Group III, claim 11, drawn to an antibody that binds to a KCNQ5 protein.

Group IV, claim 12, drawn to a method of diagnosing disease by determining the DNA sequence of a region of the KCNQ5 gene in a patient compared to a non-affected person.

Group V, claims 13-15, drawn to a method of diagnosing whether a patient carries a mutation in the KCNQ5 gene by determining the sequence of said gene and comparing it to SEQ ID NO: 1 or 2.

Group VI, claims 17-18, drawn to a method for determining whether a substance is an inhibitor of KCNQ5, or a method of identifying an inhibitor of KCNQ5, comprising measuring the biological activity of KCNQ5 by measuring membrane potassium currents.

Group VII, claims 17 and 19, drawn to a method for determining whether a substance is an activator of KCNQ5, or a method of identifying an activator of KCNQ5, comprising measuring biological activity of KCNQ5 by measuring fluorescence resonance energy transfer.

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Group VIII, claims 17 and 20, drawn to a method for determining whether a substance is an inhibitor of KCNQ5, or a method of identifying an inhibitor of KCNQ5, comprising measuring the biological activity of KCNQ5 by measuring fluorescence resonance energy transfer.

Group IX, claim 21, drawn to a method of treatment comprising administering an activator of a voltage gated potassium channel containing the KCNQ5 protein.

Group X, claim 21, drawn to a method of treatment comprising administering an inhibitor of a voltage-gated potassium channel containing the KCNQ5 protein.

4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

5. The species are as follows:

If group I or V is elected, Applicant is further required to elect:

a specific DNA encoding a KCNQ5 protein, from the group consisting of SEQ ID NO: 1 and 2,

and list all Claims readable thereon including those subsequently added. Currently claim 1 is generic with respect to DNA.

6. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

7. The inventions listed as Groups I-X and the species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reason:

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The invention of Group I, the isolated DNA, has no special technical feature that defined the contribution over the prior art U.S. Patent No. 6,492,505.

The '505 patent discloses a DNA sequence of 582 nucleic acids that is 99.6% identical to SEQ ID NO: 2 of the instant application over 524 residues (see SEQ ID NO: 303 of the '505 patent). Given the high degree of homology, said DNA would hybridize to SEQ ID NO: 2 under stringent conditions, as recited in claim 4.

8. Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and so lack unity of invention.

9. Accordingly, Groups I-X are not so linked as to form a single general inventive concept and restriction is proper.

10. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E. Juedes, Ph.D. whose telephone number is 571-272-4471. The examiner can normally be reached on 8am - 5pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

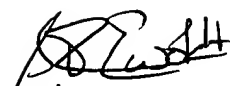
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Patent Examiner  
Technology Center 1600  
May 11, 2006

  
5/21/06  
**G.R. EWOLDT, PH.D.**  
**PRIMARY EXAMINER**